Comparison of Continuous Glucose Monitoring and Point-of-Care Measurements on the Intensive Care Unit: An exploratory study

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To investigate the discrepancy between CGM and POC measurements in insulin-dependent ICU patients and to study whether these potential discrepancies between CGM and POC vary across patient-related factors, like gender, age, comorbidities, medication…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON57040

Source
ToetsingOnline

Brief title
Continuous Glucose Monitoring on the Intensive Care Unit

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
high blood sugar, Hyperglycemia, hypoglycemia, low blood sugar

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis

Source(s) of monetary or material Support: Dexcom, Inc,Pioneers in Healthcare innovatiefonds

Intervention

Keyword: Glucose Monitoring, Insuline, Intensive care unit

Outcome measures

Primary outcome

The first main study parameter is the discrepancy, in exact values, between glucose levels measured with CGM and POC in insulin-dependent ICU patients. The other main study parameter is the variation of the potential difference in glucose levels between CGM and POC among different patient-related factors

Secondary outcome

Six secundary study parameters are defined:

1. The difference in absolute discrepancy between the glucose levels measured with CGM and POC when the CGM sensor is placed in the abdomen versus the upper arm.

2. The reported adverse events, such as infections, bleeding, and decubitus, linked to the CGM. In case of a suspected infection originating from the CGM or decubitus, the CGM will be removed.

3. The number and percentage of hypo- and hyperglycemia episodes shown by the CGM which were not detected by POC interval measurements will be recorded. A hypoglycemia in this study is defined as a glucose level < 4,0 mmol/L and a hyperglycemia is defined as a glucose level > 10,0 mmol/L.

4. The time between the onset of a hypo- or hyperglycemia and its detection via POC testing. The time is described in minutes between the first CGM measurement

below 4,0 mmol/L or above 10,0 mmol/L and the time of the POC testing below 4,0 mmol/L or above 10,0 mmol/L.

5. The duration of time, in minutes, it takes for the CGM to reliably measure after the sensor is inserted. Duration of time, in hours, the CGM reliably measures after the sensor is inserted.

6. The difference in discrepancy between the glucose levels measured with CGM and POC after radiologic procedure.

Study description

Background summary

Hyperglycaemia is present in up to 50% of patients admitted to an intensive care unit (ICU) and is strongly associated with elevated morbidity and mortality rates. Therefore, it is important to monitor glucose levels closely. In the ICU, glucose monitoring primarily relies on periodic measurements through point-of-care (POC) meters, which involve invasive blood sampling from venous or arterial lines. To maintain blood glucose concentrations better within acceptable ranges a possible improvement is continuous glucose monitoring (CGM), which is now used to manage glucose levels in diabetic patients in general settings and has shown significant benefits. Studies on the use of CGM in ICU setting are limited. If CGM is reliably measuring glucose levels in critically ills patients, it enables earlier intervention and might help to predict hypo- or hyperglycemia based on measurement trends.

Study objective

To investigate the discrepancy between CGM and POC measurements in insulin-dependent ICU patients and to study whether these potential discrepancies between CGM and POC vary across patient-related factors, like gender, age, comorbidities, medication use, disease severity scores, treatment in ICU.

Study design

Prospective, multi-centre, single-arm intervention, exploratory study.
All study participants receive one CGM sensor to monitor glucose levels. A second CGM sensor will only be applied if the first CGM sensor needed to be

replaced within 8 days after insertion. The measurements will be blinded to all except the research team.

Study burden and risks

The risks of participation in this trial are considered to be negligible. The CGM sensor is a minimally invasive tool and there are no serious risks foreseen of placing and carrying the CGM sensor. Participation in the study will not interfere with the usual care and the gold standard for glucose control (POC interval measures) will be used for insulin therapy. Part of the study population might be critically ill, incapacitated patients. Especially these patients will be insulin depended and fulfil the inclusion criteria. The required data for the study is recorded as part of standard medical care for patients admitted to the ICU (e.g. blood pressure) and no additional tests are needed. Participants will not benefit from this trial because the CGM values will be blinded to the treatment team.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients admitted to the ICU
- Insulin-dependent as defined in local protocol
- Age: >= 18 y
- Expected length of stay in ICU > 2 days

Exclusion criteria

- Pregnancy
- No informed consent
- Therapeutic hypothermia (<34 degrees celsius)
- Platelet count < 50,000/µL at time of inclusion
- Use of hydroxyurea
- Use of acetaminophen >4 g/day

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-12-2024
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	continuous glucose monitoring system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-10-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87243.100.24